

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER US Customhouse, Rm 900 2nd & Chestnut St. Philadelphia, PA 19106 (215)597-4390 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 09/17-21/2018, 09/25/2018
	FEI NUMBER 3011127887

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Monica A. Lane, Pharmacy Manager

FIRM NAME Allegheny Health Network Home Infusion, LLC	STREET ADDRESS 311 23rd St., Ext., Ste. 500
CITY, STATE AND ZIP CODE Sharpsburg, PA 15215	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drugs

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically,

On 09/20/2018, I observed an Operator donning a used disposable coverall. While donning, the legs of the coveralls contacted the floor of the Ante Room.

2. Disinfecting agents and cleaning pads or wipes used in the ISO 5 area [aseptic processing areas] are not sterile.

Specifically,

On 09/17/2018, I observed non-sterile wipes applied to surfaces within the ISO 5 area of the workbench in the non-hazard clean room, where aseptic processing of sterile products occurs. The wipes were identified as (b) (4) lint-free wipes. Products produced in the ISO 5 area workbench on 09/17/2018 include, but is not limited to the following:

- Milrinone 0.8mg/ml 165ml, Rx Number: (b) (6), Quantity: (b) (4)
- Methylprednisolone 1g/100ml, Rx Number: (b) (6), Quantity: (b) (4)

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Marcus Ray -S	EMPLOYEE(S) NAME AND TITLE (Print or Type) Marcus A. Ray, Investigator	DATE ISSUED 09/25/2018
	<small>Digitally signed by Marcus Ray -S DN: cn=Marcus Ray -S, o=U.S. Government, ou=FDA, ou=People cn=Marcus Ray -S, o=92343 19208500 100 1.1 -260152716 http://www.fda.gov/oc/industry</small>		